K011004

DIASOL INC.

MAY 2 4 2001

II. 510K SUMMARY IN ACCORDANCE WITH SMDA '90

SUBMITTER:	DIASOL INC. 13212 RAYMER ST. NORTH HOLLYWOOD, CA 91605 PHONE (818) 255-1800 FAX (818) 982-8539
CONTACT	MONICA ABELES
DATE SUMMARY WAS PREPARED	March 26, 2001
NAME OF DEVICE	NEEDLELOK HYPODERMIC NEEDLE GUARD
COMMON NAME	HYPODERMIC NEEDLE GUARD
CLASSIFICATION NAME	NEEDLE, HYPODERMIC, SINGLE LUMEN, PROTECTOR 880.5570 CLASS II
PERFORMANCE STANDARD	NONE ESTABLISHED UNDER 514 OF FDA
PREDICATE DEVICE	SIMS PORTEX NEEDLE-PRO

DEVICE DESCRIPTION:

Needlelok is a simple device designed to work with all available syringe/needle combinations sizes 1, 3, 5, 10cc.
The device slides on the syringe, shields is folded backwards. Once the procedure is finished, the shield is easily pushed back, and immediately following the needle extraction, it is closed around the needle. Not only does the shield completely enclose the needle in a secure closure, but it also bends the needle (except for 1cc syringes) though making it un-reusable.
The closure is very safe and extremely hard to override.
The device is color coded for easy identification.

Intended use of the device is as an accessory to syringe/needle combination to aid in prevention of needle stick injury.
The device is going to be used everywhere where syringes with needles are used.

The active safety feature once activated becomes permanently attached to the needle, does not interfere with the normal use of the needle and has a very simple procedure to activate.
Mount on syringe, push shield backward, and proceed with normal use. At the end of the procedure, push shield back and immediately after the needle extraction close shield. The needle will be completely covered by the shield in a very secure (almost impossible to tamper with) closure.
At the same time the needle will be bend though making it un-reusable. This does not apply for syringe/needle combination size 1cc.

The device is made of rigid plastic similar to the predicate device. The advantage is that it slides on any brand syringe and it fits 1 cc syringe making usable for syringes with permanently attached needles such as no dead space syringes.

The procedure was tested during the bench trial by a number of healthcare professionals that found it an easy, rapid one-handed technique that does not require extensive training or a change in the currently used procedure. All evaluators were able to use the device without any instruction. All evaluators were professional nurses.

The device has been tested in a variety of locations –hospitals, doctor's offices, dialysis centers.
The device performed reliable and proved to be safe in all cases.
Evaluators appreciated the fact that they can continue using the same syringes and needles as before and that the new device works well with 1cc syringe.

1/11/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2001

Ms. Monica Abeles
President
Diasol Incorporated
13212 Raymer street
North Hollywood, California 91605

Re: K011004
Trade/Device Name: Needlelok Hypodermic Needle Protection
Regulation Number: 880.5570
Regulatory Class: II
Product Code: FMI
Dated: April 4, 2001
Received: April 4, 2001

Dear Ms. Abeles

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

c. STATEMENT OF INTENDED USE

510k NUMBER

DEVICE NAME: NEEDLELOK

INDICATIONS FOR USE:

Needlelok is an accessory to a hypodermic needle/syringe combination
As a means of protection against accidental needle sticks.
The safety shield when activated provides a safe closure of the needle though aiding in needlestick injury prevention.
It is to be used any time needle/syringe is being used.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use-------
Per 21 CFR 801.109

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011004